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EXAMINER

SEREBOFF, NEAL

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,559	Applicant(s) BELLO ET AL.	
	Examiner NEAL R. SEREBOFF	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In the amendment dated 5/7/2004, the following has occurred: Claims 37 and 79 – 101 have been amended to correct numbering.

Notice to Applicant

2. Claims 1 – 101 are pending and the Information Disclosure Statement (PTO-1449) submitted on 6/23/2006 has been considered.

3. As required by MPEP § 2181(I), claims 2, 15 are being treated under 35 U.S.C. 112, 6th paragraph.

Priority

4. The Applicant has claimed priority to multiple provisional and non-provisional applications. It is not clear from the priority claim whether the claimed invention should receive priority from any of the cited applications.

Specification

5. The disclosure is objected to because of the following informalities: Claim 31 includes, “second central computer sends data from the second database to the first central computer in a first standard protocol, and the first central computer sends the data to the user interface in a second standard protocol.” The Examiner cannot find basis for this claim within the Detailed Description.

Appropriate correction is required.

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6. The disclosure is objected to because of the following informalities: Claims 68, 70, 71, 76, 78, 80, 82, 84, 86, 88, 93, 95 and 101 include the limitation “is broken down by.” It is not clear from the claims how the data is broken down.

Appropriate correction is required.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “Line Set” as described within Pre-Grant Publication paragraph 647. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claim 59 is objected to because of the following informalities: The claim includes, “vital signs date” that probably should be “vital signs data.” Appropriate correction is required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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10. Claims 49, 50 and 62 – 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 49, 50 and 62 – 64 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski, F.3d , 88 U.S.P.Q.2d 1385 (2008). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The process steps in claims (49, 50 and 62 – 64) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 2, 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim element “means for removable connection” is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The Examiner is unsure which structural means perform the function of removability.

Applicant is required to:

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(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

13. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim includes the limitation, “the medical device is a controller for a medical device.” It is not clear whether the medical device is one medical device or several devices. The Examiner understands the medical device to be one device.

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14. The term "thin client" in claim 9 is a relative term which renders the claim indefinite.

The term "thin client" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner understands 'thin client' to mean a control system for the medical device.

15. Claim 15 recites the limitation "the means for removable connection" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. ***Claims 1 – 5, 9 – 18, 21, 24, 25, 27 – 30, 40, 46 – 52*** are rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568.

18. As per claim 1, Lebel teaches a multi-purpose user interface for a healthcare system having a medical device and a first central computer, the user interface comprising:

- A housing (figure 3, #34);
- A processor (figure 3, #42);
- A memory (figure 3, #42 and paragraph 202);
- A communications interface
 - For providing communication between the user interface and the medical device (figure 3, #56) and

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- For providing communications between the user interface and the first central computer (figure 3, #32); and,
- A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36).

19. As per claim 2, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the housing comprises means for removable connection to the medical device (paragraph 27, serial interface).

20. As per claim 3, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device is a controller for a medical device (figure 3, #6).

21. As per claim 4, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to control the operation of the medical device (figure 3, #32).

22. As per claim 5, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the first central computer is structured to control the operation of the medical device (figure 3, #32).

23. As per claim 9, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface comprising:

- A thin-client operating system for operating the interface (paragraph 430); and,
- A first listener task received from the first central computer to listen for medical information from the first central computer (paragraph 162).

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24. As per claim 10, Lebel teaches the interface of claim 9 as described above. Lebel further teaches the interface comprising:

- A second listener task received from the first central computer to listen for medical information from the medical device (paragraph 162).

25. As per claim 11, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the communications interface is a wireless communications interface for communicating with a wireless access point (paragraph 155).

26. As per claim 12, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to receive status information regarding the operation of the medical device, and display the status information on the display (paragraph 250).

27. As per claim 13, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device is one of at least a volumetric infusion pump and a syringe pump (paragraph 152 or 206, syringe), and wherein the user interface is structured to program the medical device with at least one of an infusion rate, a volume to infuse, and a start time (paragraphs 3, 77, volume).

28. As per claim 14, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical prompt is an infusion prompt displayed on the display of the user interface and wherein the infusion prompt comprises an infusion prompt for at least two channels controlled by the medical device (paragraph 204, where the displayed information represents non-functional descriptive information).

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29. As per claim 15, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the means for removable connection to the medical device also comprises means for removable connection to a second medical device (paragraph 27, serial interface).

30. As per claim 16, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the communications interface also provides for communication between the user interface and a second medical device (paragraph 420).

31. As per claim 17, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the medical device is a pump controller (figure 3 and paragraph 334), and wherein the medical prompt displayed on the display of the user interface comprises a first infusion prompt for the pump controller and a second infusion prompt for a second pump controller (paragraph 138 and paragraph 420).

32. As per claim 18, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to display a selection prompt on the display for selecting at least one medical device to associate the user interface with (paragraph 222, setting operational state).

33. As per claim 21, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to receive the identification of at least one medical device to associate the user interface with (paragraph 142).

34. As per claim 24, Lebel teaches the interface of claim 1 as described above. Lebel further teaches the interface wherein the user interface is structured to send a request to the first central

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computer to locate an available and qualified clinician for the user interface (paragraph 177, alert).

35. As per claim 25, Lebel teaches the interface of claim 24 as described above. Lebel further teaches the interface wherein the first central computer sends a message to a clinician device that the user interface is in need of attention, and receives a response from the clinician device that the clinician will attend to the user interface (paragraph 159, emergency notification).

36. As per claim 27, Lebel teaches a healthcare system for use in a care-giving facility, comprising:

- A medical device (figure 3, implantable);
- A first central computer (figure 3, External Subsystem); and,
- A multi-purpose user interface having
 - A housing (figure 3, #34),
 - A processor (figure 3, #42),
 - A memory (figure 3, #42 and paragraph 202),
 - A communications interface
 - For Providing communication between the user interface and the medical device (figure 3, #56)and
 - For providing communications between the user interface and the first central computer (figure 3, #32), and
 - A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36).

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The Examiner understands the first central computer and the multi-purpose interface being the same device or a computer with a monitor.

37. As per claim 28, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system wherein the first central computer is a medical device server structured to utilize web services for communication with the medical device and to the user interface (paragraph 159).

38. As per claim 29, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system wherein the first central computer is structured to send a first script to the medical device to perform a first task (paragraph 161 and 162) and is structured to send a second script to the user interface to perform a second task (paragraph 161 and 162).

39. As per claim 30, Lebel teaches the system of claim 29 as described above. Lebel further teaches the system wherein the first and second tasks are one of at least a listen task, an alarm task, an alert task, a message task, a low battery task, an occlusion task, a pre-occlusion task, a bolus task, a KVO task, a STAT task, a change order task, a new order task, a lab result task, an MRI results task, an update task, a change in telemetry data task, a change in vital signs task, a doctor contact task, a patient contact task, a loss of communications task, a relay of message from other device task; and a new rate task (relay of message through sound and bolus).

40. As per claim 40, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- A plurality of wireless access points through which the medical device and the user interface communicate with the first central computer (paragraph 420, multiple implantable devices).

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41. As per claim 46, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- A plurality of wireless access points for communication among the user interface, the medical device, and the first central computer (paragraph 420, multiple implantable devices).

42. As per claim 47, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising a second medical device (paragraph 420), wherein the user interface housing is structured to provide for removable connection to the second medical device (figure 5, multiple serial connections).

43. As per claim 48, Lebel teaches the system of claim 27 as described above. Lebel further teaches the system comprising:

- Wherein the medical device has an alarm/alert module that identifies the existence of at least one of an alarm or alert condition (paragraph 177),
- Wherein the first central computer is structured to receive a signal from the alarm/alert module or from the multi-purpose user interface relating to the alarm or alert condition (paragraph 177),
 - The first central computer further having a timer module that sets a timer limit (paragraphs 27 – 40),
- The multi-purpose user interface having a receiver that receives an alarm or alert condition signal from the first central computer or from the medical device (figure 1, #44),

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- Wherein the user interface is further structured to display text or an icon representative of the alarm/alert condition signal (the displayed information is non-functional descriptive information), and
 - To provide an audible alarm or alert representative of the received alarm/alert condition signal (figure 1, #44 and paragraph 202), and
- Wherein the first central computer escalates the alarm or alert condition signal if no response to the alarm or alert condition signal is received from either the medical device or from the user interface within the timer limit (paragraph 276, where the system resets itself).

44. As per claim 49, Lebel teaches a method for a healthcare system within a care-giving facility, the system having a medical device, a first central computer, and a multi-purpose user interface, the method comprising the steps of:

- Providing for receiving first medical data from the medical device at the first central computer (figure 1, #56);
- Providing for receiving second medical data from the user interface at the first central computer (figure 1, #56, where multiple data is sent and paragraph 420, multiple pumps);
- Providing for sending third medical data to the user interface from the first central computer (figure 1, #36); and,
- Providing for sending a communication task to the user interface from the first central computer for providing at least one communication capability for communication between the medical device and the user interface (paragraph 132, display where the displayed data represents non-functional descriptive information).

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45. As per claim 50, Lebel teaches the method of claim 49 as described above. Lebel further teaches the method comprising the step of:

- Providing for sending fourth medical data to the medical device from the first central computer, the fourth medical data comprising operating parameters for operating the medical device (paragraph 73 and 74).

46. As per claim 51, Lebel teaches a multi-purpose user interface for a healthcare system having a medical device and a first central computer, the user interface comprising:

- A housing (figure 3, #34);
- A processor (figure 3, #42);
- A memory (figure 3, #42 and paragraph 202);
- A communications interface for providing communications between the user interface and the first central computer (figure 3, #56); and,
- A display for displaying a medical prompt and for displaying medical information received from the first central computer (figure 3, #36),
 - Wherein the medical prompt requests input on directing the first central computer to send operating parameters to the medical device (paragraphs 188 – 192).

47. As per claim 52, Lebel teaches the user interface of claim 51 as described above. Lebel further teaches the user interface wherein the medical prompt is generated at the first central computer and sent to the display of the user interface from the first central computer (paragraph 132).

48. **Claims 54 – 66, 73, 75, 77, 79, 81, 83, 85, 87, 89 – 91, 96, 97** are rejected under 35 U.S.C. 102(b) as being anticipated by Blomquist, U.S. Pre-Grant Publication 2002/ 0029776.

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49. As per claim 54, Blomquist teaches a system for monitoring healthcare data, comprising:

- A medication delivery pump for infusing a solution, the pump having a first location, the pump having first healthcare data associated therewith (figure 1, #110);
- A monitor proximate the first location, the monitor having second healthcare data associated therewith (figure 1, #104);
- A central computer for receiving the first and second healthcare data (figure 1, #102); and,
- An interface device in communication with the central computer, for displaying at least a portion of each of the first and second healthcare data on a single interface screen on the interface device (figure 1, #102 or #104, figure 2 and paragraph 40).

50. As per claim 55, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the interface device is separate from the infusion pump and vital signs monitor (figure 1, #102 where the Examiner understands that the vital signs monitor is the proximate monitor of claim 54).

51. As per claim 56, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the interface device is remote from the first location (paragraph 38).

52. As per claim 57, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the central computer manipulates the first and second healthcare data to combine at least the portion of each of the first and second healthcare data for use in displaying on the interface device (paragraph 98).

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53. As per claim 58, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the first healthcare data comprises at least one of pump alarm data, pump alert data, medication being infused data, medication to be infused data, rate of infusion data, medication dose data, volume to be infused data, volume already infused data, volume left to be infused data, infusion time data, time left for infusion data, time elapsed for infusion data, order comparison data, limits data, patients with active infusions data, channels being used for pump data, location of pump data, pumps on standby data, pumps running data, pumps stopped data, and infusion near end alert data (paragraph 88, dosage).

54. As per claim 59, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the second healthcare data comprises at least one of vital signs data, arrhythmia data, hemodynamic data (paragraph 50, vital signs).

55. As per claim 60, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system wherein the medication delivery pump comprises at least one of a MEMS pump and an infusion pump (paragraph 2, pumps for infusing).

56. As per claim 61, Blomquist teaches the system of claim 54 as described above.

Blomquist further teaches the system

- Wherein the interface device further comprises options for programming and/or managing the pumps (paragraph 100),
- Wherein the options comprise at least one of clearing the volume infused at the end of a shift, silencing alarms and alerts, accessing documentation of titration history, accessing an eMAR, accessing clinical documentation, and accessing information on comparisons

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of drug label, rate/dose, or concentration data programmed on infusion pump to a pre-defined list of high and low dose or concentration limits (paragraph 100, history).

57. As per claim 62, Blomquist teaches a method for monitoring healthcare data within a healthcare system, comprising the steps of:

- Receiving first healthcare data associated with a medication delivery pump for infusing a solution, the pump having a first location (paragraph 58);
- Receiving second healthcare data associated with a monitor proximate the first location (paragraph 50); and,
- Sending at least a portion of each of the first and second healthcare data to an interface device for display on a single interface screen through the interface device (paragraph 59 – 70 where the displayed information is non-functional descriptive information).

58. As per claim 63, Blomquist teaches the method of claim 62 as described above.

Blomquist further teaches the method comprising the step of manipulating at a central computer the first and second healthcare data to combine at least the portion of each of the first and second healthcare data for use in displaying on the interface device (paragraph 59 – 70 where the displayed information is non-functional descriptive information).

59. As per claim 64, Blomquist teaches the method of claim 62 as described above.

Blomquist further teaches the method comprising the step of receiving a request from the interface device, the request comprising at least one of a programming request and a management request (paragraph 55, programming).

60. As per claim 65, Blomquist teaches a system for tracking and reporting healthcare system data, comprising:

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- A first medical pump having first medical pump data associated therewith (figure 1, #110);
- A second medical pump having second medical pump data associated therewith (figure 1, additional #110);
- A central computer in communication with the first and second medical pumps over a communications network, for receiving and storing the first and second medical pump data (figure 1, #102); and,
- An interface device having an interface screen for displaying a manipulated version of the first and second medical pump data (figure 1, #102, figure 2 and paragraph 40).

61. As per claim 66, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the central computer processes the first and second medical pump data to create the manipulated version of the first and second medical pump data by at least one of totalizing, calculating, combining, comparing, analyzing, computing, and tabulating the first and second medical pump data (figure 1, #106 and paragraph 117, combining).

62. As per claim 73, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of scan error data, source of scan data, scan type data (item or patient), expected scan data, and actual scan data (paragraph 107, where the data represents non-functional descriptive information).

63. As per claim 75, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second

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medical pump data comprises at least one of total administrations data, total wrong time data, reason data, medication data, patient data, order data, order administration time data, administration time data, early medication data, late medication data, expired medication data, and missed medication data (paragraph 107, medication data where the data represents non-functional descriptive information).

64. As per claim 77, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusions data, matches data, resolved mismatches data, accepted mismatches data, and no comparisons data (paragraph 107, infusion data).

65. As per claim 79, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of no match data, match data, and no comparison data (paragraph 107, where match data is the infusion data).

66. As per claim 81, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusions data, rate matches data, rate resolved mismatches data, rate accepted mismatches data, rate no comparisons data, mode mismatches data (paragraph 107, infusion data).

67. As per claim 83, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of unit data, patient data, nurse data, order data,

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administration data, occurrence data date, pump mode data, pump status data, rate data, comparison data, and dose data (paragraph 107, patient data).

68. As per claim 85, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusion data, alert data, reprogramming after alert data, accepted alert override data, and label data (paragraph 107, infusion data).

69. As per claim 87, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of infusion data, KVO alert data, alarm data, alarm by code data, alarm by device data, alert by code data, alert by device data, alarm code data, alert code data, escalation data, escalation level data, patient data, nurse data, order data, source data, device data, mode data, occurrence data, cleared time data, silenced time data, response time data, alarm condition data, mode data, and medication data (paragraph 107, infusion data).

70. As per claim 89, Blomquist teaches the system of claim 65 as described above.

Blomquist further teaches the system wherein the interface device is a pharmacist interface device (paragraph 111), and wherein the manipulated version comprises at least one of pump status data for all connected pumps in a unit, pump status data for all connected pumps in a hospital, pump status data for all connected pumps which are active in the unit, pump status data for all connected pumps which are active in the hospital (paragraphs 57 – 69 and paragraph 81, 82).

71. As per claim 90, Blomquist teaches a system for tracking and reporting healthcare system data, comprising:

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- A plurality of interface devices, at least one of the interface devices having a receiver for receiving identifier data (figure 1); and,
- A central computer in communication with the plurality of interface devices over a communications network, for receiving and storing the identifier data (figure 1, #102),
 - Wherein at least one of the plurality of interface devices having an interface screen for displaying a manipulated version of the identifier data (figure 1, #104).

72. As per claim 91, Blomquist teaches the system of claim 90 as described above.

Blomquist further teaches the system wherein the central computer processes the identifier data to create the manipulated version of the identifier data by at least one of totalizing, calculating, combining, comparing, analyzing, computing, and tabulating the identifier data or the use thereof in delivering medication (figure 1, #106 and paragraph 117, combining).

73. As per claim 96, Blomquist teaches the system of claim 91 as described above.

Blomquist further teaches the system comprising:

- A first medical pump having first medical pump data associated therewith (figure 1);
- A second medical pump having second medical pump data associated therewith (figure 1),
 - Wherein the central computer is in communication with the first and second medical pumps over the communications network, for receiving and storing the first and second medical pump data (figure 1, #102),
 - Wherein the at least one interface device having an interface screen for displaying a manipulated version of the first and second medical pump data and the

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manipulated version of the identifier data by hospital unit and totaled together (figure 1, #102 or #104, figure 2 and paragraph 40).

74. As per claim 97, Blomquist teaches the system of claim 90 as described above.

Blomquist further teaches the system wherein the manipulated version of the identifier data comprises at least one of scan error data, source of scan data, scan type data (item or patient), expected scan data, and actual scan data (paragraph 107, where the data represents non-functional descriptive information).

75. As per claim 99, Blomquist teaches the system of claim 90 as described above.

Blomquist further teaches the system wherein the criteria comprises at least one of time, date, device, unit, screen, bar code type, screen type, user group, and user (paragraph 96, bar code).

76. As per claim 100, Blomquist teaches the system of claim 90 as described above.

Blomquist further teaches the system wherein the manipulated version of the identifier data comprises at least one of total administrations data, total wrong time data, reason data, medication data, patient data, order data, order administration time data, administration time data, early medication data, late medication data, expired medication data, and missed medication data (paragraph 96, medication data where the data represents non-functional descriptive information).

Claim Rejections - 35 USC § 103

77. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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78. **Claims 6 – 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Olsen, U.S. Pre-Grant Publication 2002/ 0173774.

79. As per claim 6, Lebel teaches the interface of claim 1 as described above.

Lebel does not explicitly teach the interface wherein the medical device is a MEMS Pump (paragraph 205, other pump).

However, Olsen further teaches the interface wherein the medical device is a MEMS Pump (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

80. As per claim 7, Lebel teaches the interface of claim 6 as described above.

Lebel further teaches the interface wherein the pump is integral with a line set (paragraph 117).

Lebel does not explicitly teach the interface wherein the MEMS pump is integral with a line set.

However, Olsen further teaches the interface wherein the MEMS pump is integral with a line set (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

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- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

81. As per claim 8, Lebel teaches the interface of claim 6 as described above.

Lebel further teaches the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface (paragraph 157).

Lebel does not explicitly teach the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface.

However, Olsen further teaches the interface wherein the MEMS pump comprises an identifier for identifying the MEMS pump to at least one of the first central server and the user interface (paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The prior art differs from the claim by the substitution of some components. The substituted components were known. The technical ability existed to substitute the components as claimed and the result of the substitution is predictable.

82. ***Claims 19, 20, 22 and 23*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568.

83. As per claim 19, Lebel teaches the interface of claim 18 as described above.

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Lebel further teaches the interface wherein the at least one medical device is of a first type and another medical device is of a second type (paragraph 420).

Lebel does not explicitly teach the interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

However, it would be a matter of prima facie obvious design choice to configure an interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

84. As per claim 20, Lebel teaches the interface of claim 19 as described above. Lebel further teaches the interface wherein the first and second types are selected from a group consisting of an infusion pump personality, a syringe pump personality, and a pulse oximeter (paragraph 413).

85. As per claim 22, Lebel teaches the interface of claim 21 as described above. Lebel further teaches the interface wherein the at least one medical device is of a first type and another medical device is of a second type (paragraph 413 and 420).

Lebel does not explicitly teach the interface wherein the user interface is structured to operate in accordance with a first personality associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

However, it would be a matter of prima facie obvious design choice to configure an interface wherein the user interface is structured to operate in accordance with a first personality

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associated with the first type and is structured to operate in accordance with a second personality associated with the second type.

86. As per claim 23, Lebel teaches the interface of claim 22 as described above. Lebel further teaches the interface wherein the processor automatically programs the user interface to operate in accordance with the first type upon receipt of the identification of the at least one medical device (paragraph 203, closed loop).

87. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of McDevitt et al., U.S. Pre-Grant Publication 2003/ 0064422.

88. As per claim 26, Lebel teaches the interface of claim 1 as described above.

Lebel does not explicitly teach the interface wherein at least a subset of communications sent and received by the communications interface are secure communications.

However, McDevitt further teaches the interface wherein at least a subset of communications sent and received by the communications interface are secure communications (paragraph 432, encryption).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to encrypt for security purposes (McDevitt paragraph 416).

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89. *Claims 31 – 36, 39, 41, 43 and 44* are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776.

90. As per claim 31, Lebel teaches the system of claim 27 as described above.

Lebel further teaches the system comprising

- The first central computer comprises a first database and a first functional feature set (paragraph 27),

Lebel does not explicitly teach the system comprising

- The healthcare system further comprising
 - A second central computer having a second database and a second functional feature set, and
 - Wherein the user interface can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer.

However, Blomquist further teaches the system comprising

- The healthcare system further comprising
 - A second central computer having a second database and a second functional feature set (figure 1, #102 and #106), and

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- Wherein the user interface can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer (figure 1, #108, Ethernet).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

91. As per claim 32, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first functional feature set comprises at least one of a volumetric infusion pump feature and a syringe pump feature (paragraph 152 or 206, syringe).

92. As per claim 33, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first functional feature set comprises at least one of a change pump channel feature, an administer infusion feature, a stop or discontinue infusion feature, a resume infusion feature, and a remove pump feature (paragraph 180, stop).

93. As per claim 34, Lebel in view of Blomquist teaches the system of claim 31 as described above.

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Lebel does not explicitly teach the system wherein the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature, an alarms/alerts feature, a billing interface feature, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature.

However, Blomquist further teaches the system wherein the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature, an alarms/alerts feature, a billing interface feature, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature (paragraph 111 and figure 8, facility management with multiple pumps).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

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- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

94. As per claim 35, Lebel in view of Blomquist teaches the system of claim 31 as described above. Label further teaches the system wherein the first database comprises at least one of pump data, pump channel data, pump sub-channel data, order data, clinician data, patient data, user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data (paragraph 196, pump data).

95. As per claim 36, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the second database comprises at least one of patient management data, item management data, facility management data, messaging data, alarms/alerts data, inventory tracking data, clinician administration data, order entry data, user interface and clinician association data.

However, Blomquist further teaches the system wherein the second database comprises at least one of patient management data, item management data, facility management data, messaging data, alarms/alerts data, inventory tracking data, clinician administration data, order entry data, user interface and clinician association data (paragraph 111 and figure 8, facility management with multiple pumps).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

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- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

96. As per claim 39, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database, and wherein the first central computer sends the combined first and second data to the user interface for display on a display of the user interface.

However, Blomquist further teaches the system wherein the second central computer sends second data from the second database to the first central computer (paragraph 109, downloaded to the pump), wherein the first central computer combines the second data with first data from the first database (paragraph 109), and wherein the first central computer sends the combined first and second data to the user interface for display on a display of the user interface (paragraph 109).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

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- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.
When combined, the elements perform the same function as they did separately.
- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

97. As per claim 41, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label does not explicitly teach the system wherein the first central computer receives second data from the second database in the second central computer for use in a validation procedure.

However, Blomquist further teaches the system wherein the first central computer receives second data from the second database in the second central computer for use in a validation procedure (paragraph 55, not corrupt).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.
When combined, the elements perform the same function as they did separately.
- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

98. As per claim 43, Lebel in view of Blomquist teaches the system of claim 31 as described above.

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Label does not explicitly teach the system wherein the first central computer is structured to receive patient order information from the second central computer and structured to receive medical device programming information from at least one of the medical device and the user interface, and wherein the first central computer is structured to compare the patient order information with the medical device programming information to determine if the medical device programming information is accurate, and wherein the first central computer is structured to send a result of the comparison to at least one of the medical device and the user interface.

However, Blomquist further teaches the system wherein the first central computer is structured to receive patient order information from the second central computer and structured to receive medical device programming information from at least one of the medical device and the user interface, and wherein the first central computer is structured to compare the patient order information with the medical device programming information to determine if the medical device programming information is accurate, and wherein the first central computer is structured to send a result of the comparison to at least one of the medical device and the user interface (paragraph 109, where the design of the network is further a matter of prima facie design choice).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

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- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

99. As per claim 44, Lebel in view of Blomquist teaches the system of claim 43 as described above.

Label does not explicitly teach the system wherein the result is sent from the first central computer to user interface to the medical device.

However, Blomquist further teaches the system wherein the result is sent from the first central computer to user interface to the medical device (paragraph 109).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to create a library of pump data on a computer having a database (Blomquist paragraph 7).

100. ***Claims 37, 38 and 45*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 as applied above to claim 31, further in view of McDevitt et al., U.S. Pre-Grant Publication 2003/ 0064422.

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101. As per claim 37, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label in view of Blomquist do not explicitly teach the system wherein the first central computer is operably connected to the second computer through a dedicated TCP/IP hard-wired connection.

However, McDevitt further teaches the system wherein the first central computer is operably connected to the second computer through a dedicated TCP/IP hard-wired connection (paragraph 430).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added this feature into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to use an existing Internet protocol (McDevitt paragraph 426).

102. As per claim 38, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label in view of Blomquest do not explicitly teach the system wherein the second central computer sends data from the second database to the first central computer in a first standard protocol, and the first central computer sends the data to the user interface in a second standard protocol.

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However, McDevitt further teaches the system wherein the second central computer sends data from the second database to the first central computer in a first standard protocol (paragraph 426, tcp/ip), and the first central computer sends the data to the user interface in a second standard protocol (paragraph 446, http).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to use an existing Internet protocol (McDevitt paragraph 426).

103. As per claim 45, Lebel in view of Blomquist teaches the system of claim 31 as described above.

Label in view of Blomquest do not explicitly teach the system wherein the first central computer is securely connected to the second computer, and wherein the medical device and the user interface do not communicate directly with the second central computer.

However, McDevitt further teaches the system wherein the first central computer is securely connected to the second computer (paragraph 442), and wherein the medical device and the user interface do not communicate directly with the second central computer (figure 66, network cloud verses a point to point direct connection).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to use an existing Internet protocol (McDevitt paragraph 426).

104. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 as applied above to claim 41, further in view of Callahan et al., U.S. Pre-Grant Publication 2004/ 0029213.

105. As per claim 42, Lebel in view of Blomquist teaches the system of claim 41 as described above.

Label does not explicitly teach the system wherein the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

Blomquist further teaches the system wherein the validation procedure comprises the steps of determining whether the data expected to be received is received (paragraph 73).

Label in view of Blomquist do not explicitly teach the system wherein the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

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However, Callahan further teaches the system wherein the validation procedure comprises the steps of receiving an XML document (figure 14 and paragraph 124, where the data is stored as XML) and determining whether the data expected to be received from the XML document is received.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel in view of Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Lebel in view of Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

106. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., U.S. Pre-Grant Publication 2002/ 0016568 in view of DeLaHueriga, U.S. Pre-Grant Publication 2002/ 0116509.

107. As per claim 53, Lebel teaches the user interface of claim 52 as described above.

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Lebel does not explicitly teach the user interface wherein the medical prompt is sent in the form of an html page and displayed on the display with a browser application running on the user interface.

However, DeLaHuergera further teaches the user interface wherein the medical prompt is sent in the form of an html page (paragraph 401) and displayed on the display with a browser application running on the user interface (paragraphs 401).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Lebel. One of ordinary skill in the art at the time of the invention would have added these features into Lebel

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

- With the motivation to intelligibly receive a transmitted message and provide information contained therein to a browser for ultimate delivery to a server for storage or processing, a message receiving computer must be capable of translating the transmitted message into the language used by the server which is typically the hypertext markup language (DeLaHuergera, paragraph 32).

108. ***Claims 67 – 72, 92 and 94*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist, U.S. Pre-Grant Publication 2002/ 0029776 in view of Martrucci et al., U.S. Pre-Grant Publication 2004/ 0104271.

109. As per claim 67, Blomquist teaches the system of claim 65 as described above.

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Blomquist does not explicitly teach the system wherein the manipulated version of the first and second medical pump data comprises near misses for the first and second pumps.

However, Martrucci further teaches the system wherein the manipulated version of the first and second medical pump data comprises near misses for the first and second pumps (paragraph 35, incorrect settings).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

110. As per claim 68, Blomquist in view of Martrucci teaches the system of claim 67 as described above.

Blomquist does not explicitly teach the system wherein the near misses are broken down by medication.

However, Martrucci further teaches the system wherein the near misses are broken down by medication (figure 32(b) where the displayed data represents non-functional descriptive information).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

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- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

The storage of data within a database represents prima facie obvious design choice to make the data separable or integral.

111. As per claim 69, Blomquist teaches the system of claim 65 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the first and second medical pump data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data.

However, Martrucci further teaches the system wherein the manipulated version of the first and second medical pump data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data (paragraph 35, wrong drug data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

112. As per claim 70, Blomquist in view of Martrucci teaches the system of claim 69 as described above.

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Blomquist does not explicitly teach the system wherein the manipulated version of the first and second medical pump data is broken down by at least one of unit, infusion, non-infusion and medication.

However, the storage of data within a database represents prima facie obvious design choice to make the data separable or integral.

113. As per claim 71, Blomquist in view of Martrucci teaches the system of claim 70 as described above.

Blomquist further teaches the system

- Wherein the central computer is further provided for receiving and storing first non-pump medication delivery data and second non-pump medication delivery data (paragraph 107 where the data represents non-functional descriptive information. The storing of data within a database represents prima facie design choice),
- Wherein the interface device is further provided for displaying a manipulated version of the first and second non-pump medication delivery data (paragraph 106, where the displayed data represents non-functional descriptive information), and
- Wherein the manipulated version of the first and second non-pump medication delivery data is broken down by hospital unit and totalized with the manipulated version of the first and second medical pump data (paragraph 107, the storage of data within a database represents prima facie obvious design choice to make the data separable or integral).

114. As per claim 72, Blomquist in view of Martrucci teaches the system of claim 69 as described above.

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Blomquist does not explicitly teach the system wherein near miss wrong time comprises at least one of late delivery, early delivery, and missed delivery.

However, Martrucci further teaches the system wherein near miss wrong time comprises at least one of late delivery, early delivery, and missed delivery (figure 15(i), late delivery).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

115. As per claim 92, Blomquist teaches the system of claim 90 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the identifier data comprises near misses relating to the use of the identifier data.

However, Martrucci further teaches the system wherein the manipulated version of the identifier data comprises near misses relating to the use of the identifier data (figure 15(i), late delivery).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

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116. As per claim 94, Blomquist teaches the system of claim 90 as described above.

Blomquist does not explicitly teach the system wherein the manipulated version of the identifier data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data.

However, Martrucci further teaches the system wherein the manipulated version of the identifier data comprises at least one of near miss wrong drug data, near miss wrong time data, near miss wrong route data, near miss wrong dose data, and error wrong dose data (paragraph 35, wrong drug data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add these features into Blomquist. One of ordinary skill in the art at the time of the invention would have added these features into Blomquist

- The elements are all known but not combined as claimed. The technical ability exists to combine the elements as claimed and the results of the combination are predictable.

When combined, the elements perform the same function as they did separately.

117. ***Claims 74, 76, 78, 80, 82, 84, 86, 88, 93, 95, 98 and 101*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist, U.S. Pre-Grant Publication 2002/ 0029776.

118. As per claim 74, Bloomquist teaches the system of claim 65 as described above.

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Bloomquist does not explicitly teach the system wherein the interface device comprises a second interface screen for selecting criteria to display the manipulated version of the first and second medical pump data.

However, the design of the computer display is a matter of prima facie obvious design choice.

119. As per claim 76, Bloomquist teaches the system of claim 75 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, infusion, non-infusion, nurse, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

120. As per claim 78, Bloomquist teaches the system of claim 77 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of type of infusion and unit.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

121. As per claim 80, Bloomquist teaches the system of claim 79 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of infusion type, medication type, volume, infusion route, total, unit, primary and piggyback.

Art Unit: 3626

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

122. As per claim 82, Bloomquist teaches the system of claim 81 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, mode, medication, and patient.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

123. As per claim 84, Bloomquist teaches the system of claim 83 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, patient, nurse, order, and administration.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

124. As per claim 86, Bloomquist teaches the system of claim 85 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit and label.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

125. As per claim 88, Bloomquist teaches the system of claim 87 as described above.

Art Unit: 3626

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, alarm condition, alert condition, alarm code, alert code, patient, nurse, order, occurrence time, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

126. As per claim 93, Bloomquist teaches the system of claim 92 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated data is broken down by at least one of unit, infusion, non-infusion, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

127. As per claim 95, Bloomquist teaches the system of claim 90 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version of the identifier data is broken down by hospital unit and totalized.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

128. As per claim 98, Blomquist teaches the system of claim 90 as described above.

Blomquist does not explicitly teach the system wherein the interface device comprises a second interface screen for selecting criteria to display the manipulated version of the identifier data.

However, the design of the computer display is a matter of prima facie obvious design choice.

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129. As per claim 101, Bloomquist teaches the system of claim 100 as described above.

Bloomquist does not explicitly teach the system wherein the manipulated version is broken down by at least one of unit, infusion, non-infusion, nurse, and medication.

However, the design of the computer display or the storage of data within a database is a matter of prima facie obvious design choice. Additionally, the displayed or stored data is non-functional descriptive information.

Conclusion

130. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zerhusen et al., U.S. Pre-Grant Publication 2003/ 0052787

Childers et al., U.S. Pre-Grant Publication 2003/ 0220609

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/N. R. S./

Examiner, Art Unit 3626

3/11/2009

/Robert Morgan/

Primary Examiner, Art Unit 3626